510(k) SUMMARY

FEB 13 2007

SAPPHIRE MEDICAL, INC.
CINCH™ BONE ANCHOR SYSTEM

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Sapphire Medical, Inc
690 Oak Grove Avenue
Menlo Park, CA 94025

Phone: 650-322-3544
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Contact Person: Brooke Campbell

Date Prepared: September 13, 2006

Name of Device and Name/Address of Sponsor

CINCH Bone Anchor System

Sapphire Medical, Inc
690 Oak Grove Avenue
Menlo Park, CA 94025

Common or Usual Name

Bone Anchor

Classification Name

Classification: Class II
Classification Name: Fastener, fixation, nondegradable, soft tissue.

Predicate Devices

- DePuy/Mitek Products, Rotator Cuff QuickAnchor® Plus
- Linvatec Corporation, UltraFix® RC
- ArthroCare Corporation, Opus® Magnum
- Arthrex, Inc., PEEK Corkscrew FT
- Smith & Nephew, Inc., BioRaptor 2.9 Suture Anchor

Intended Use / Indications for Use

The CINCH Bone Anchor System is intended to be used for fixation of soft tissue to bone during rotator cuff repair.

Device Description

The CINCH Bone Anchor System provides surgeons with a fixation anchor that can be used during arthroscopic shoulder procedures. The device is available in two configurations, the CINCH WRC Anchor and the CINCH RRC Anchor. Both configurations are provided pre-loaded in a delivery instrument.

The CINCH WRC Anchor configuration is comprised of a curved PEEK base, a flared nitinol clip, two nitinol laser cut rings and a nitinol anchor pin. The device is preloaded in the CINCH Inserter

The CINCH RRC Anchor, is comprised of a machine molded cylindrical PEEK base, two nitinol laser cut rings and a nitinol anchor pin This device is also preloaded in a CINCH Inserter.

The design of the CINCH Bone Anchors is intended to permit surgeons to have direct tactile feedback of the tension in the suture between the tissue and the bone. Additionally, the CINCH Anchors are designed to allow the two ends of a suture to be individually adjusted. This permits the surgeon to fine-tune the placement of the tissue with respect to the bone, and then secure the suture without tying a knot.

Performance Data

Results of bench testing demonstrate that the CINCH Bone Anchor System meets its specifications and does not raise new issues of safety or effectiveness. In all instances, the CINCH Bone Anchor functioned as intended.

Biocompatibility Data

The materials used in the CINCH Bone Anchor System are biocompatible. The same materials are commonly used in similar medical devices.

Substantial Equivalence

The CINCH Bone Anchor System is substantially equivalent to the DePuy/Mitek Products' Rotator Cuff QuickAnchor® Plus, Arthrex, Inc.'s PEEK Corkscrew FT, Smith & Nephew, Inc.'s BioRaptor 2.9 Suture Anchor, and Linvatec Corporation's UltraFix® RC. The CINCH Bone Anchor System has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. The minor technological differences between the CINCH Bone Anchor System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the CINCH Bone Anchor System is as safe and effective as the predicate devices. Thus, the CINCH Bone Anchor System is substantially equivalent.

Summary

Based on the intended use, technological characteristics, and performance information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sapphire Medical, Inc.
% Janice M. Hogan, Esq.
Partner
Hogan & Hartson, L.L.P.
1835 Market Street, 28th Floor
Philadelphia, Pennsylvania 19103

FEB 13 2007

Re: K062739
Trade/Device Name: CINCH Bone Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: January 26, 2007
Received: January 26, 2007

Dear Ms. Hogan:

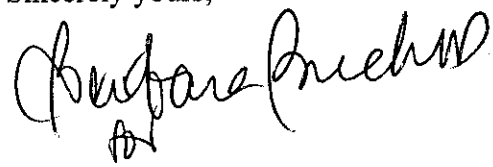
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K062739

Device Name: CINCH Bone Anchor System

Indications for Use:

The CINCH Bone Anchor System is intended for the fixation of soft tissue to bone during rotator cuff repair.

Prescription Use ____X (Part 21 C.F.R. 801 Subpart D) AND/OR Over-The-Counter Use____ (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Boehm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062739